

How LIMS Ensures Product Quality and Facilitates ISO Certification

By Paula Hollywood

Summary

The wealth of information analytical measurements provide has placed increased importance on integrating this information into higher-level enterprise application platforms. A well-designed quality management system that includes an integrated LIMS is critical to ensuring product quality and customer satisfaction.

Industries across the board are coping with relentless pressure to reduce costs while improving product quality at the same time. Hydrocarbon processors have an additional challenge in achieving higher product quality as a result of the heavier raw materials available for processing. Heavier crude feedstock from sources such as the Canadian tar sands have high sulfur content making them more complex and expensive to refine. This heavier feedstock is in direct contrast to requirements for low sulfur products dictated by ever more stringent regulatory requirements. In this environment, a well-designed quality management system (QMS) that includes a robust laboratory information management system (LIMS) that facilitates ISO 17025:2005 accreditation is critical to ensuring product quality and customer satisfaction.

LIMS Is Vital to Quality Management

What does quality cost and what's the potential harm of shipping an out-of-spec hydrocarbon? Here's an example: In July 2010, Kellogg Co. recalled an estimated 28 million boxes of breakfast cereal from store shelves due to an "off-flavor and smell" causing illness in some consumers. Chemical analysis determined that the cereal itself was not contaminated, and independent toxicologists concluded that the paraffin wax used as a protective coating on the package liners contained elevated levels of aromatic hydrocarbons, including methylnaphthalene, as the source of the problem. In this case, the elevated aromatic hydrocarbon levels were not deemed to be harmful, but Kellogg vowed to work with its suppliers guard against a repeat occurrence. And how will this be accomplished? A detailed review of the supplier's quality control process should be among the first steps in correcting what was likely a product variability issue.



The price manufacturers pay for quality may be difficult to quantify but costly examples are not hard to find. Inspection systems that perform product sampling and chemical analyses cost money yet they can be easily justified. Reprocessing or scrapping product wastes time, money, and resources. Furthermore, off-spec product can lead to unhappy customers or worse, product recalls that have the potential to damage the brand as well as the manufacturer's corporate image. At the other end of the spectrum, product quality over and above that required by contractual obligations incurs additional costs for which manufacturers are not compensated impacts margins and profitability.

A comprehensive quality management system with an integrated LIMS can help to reduce product variability as well as improve operational performance. In hydrocarbon processing, lower grade feedstock may dictate higher in-process sampling and analysis rates to prevent defects during the manufacturing process. When integrated with MES and ERP systems, quality-related information generated by the LIMS is accessible to production and other departments to ensure products meet defined specifications and demonstrate compliance with regulatory, product, and safety standards.

A comprehensive quality management system with an integrated LIMS like Thermo Scientific SampleManager can help to reduce product variability as well as improve operational performance.

A LIMS such as Sample Manager 10 from Thermo Fisher Scientific adds value to QA/QC control systems

with full traceability functionality and serves as a repository for documents and reports as evidence of compliance. LIMS can provide vital information at the front-end of the manufacturing cycle. Identifying off-spec raw materials upon inspection can provide the needed heads-up to tune the production process to yield acceptable final product(s). It can demonstrate that a sample was appropriately handled and that the analysis was performed by a properly trained, qualified technician. It can act as a repository for laboratory equipment and maintenance histories or analytical method validation as well as the corporate quality manual. LIMS data can also be useful in determining the appropriate corrective action for off-spec product and to evaluate the performance of the quality system. Upon final QA quality and contamination checks, it can quickly release shipments.

If it has been determined a non-compliant lot was inadvertently shipped, fast efficient flow of information will ensure a recall can be quickly implemented. Without traceability records from LIMS, it would be nearly impossible to accomplish product recalls in a timely and controlled manner.

Integrated LIMS Enhance Quality Control

In the manufacturing environment, analytical measurements define the who, what, when, where and how of a manufacturing process. As the backbone of the laboratory, a LIMS provides quantitative and qualitative information about chemical processes for enhanced quality control. The wealth of information analytical measurements provide has placed increased importance on integrating this information into higher-level enterprise application platforms. To improve response to operational issues, managers look to technology to connect plant floor and business systems, like ERP, PIMS and MES, making it critical that analytical information be presented to the viewer in the context of their role, responsibility, and authority. For real-time quality management, information visibility is the driver behind the demand for better integration of laboratory-generated information throughout the enterprise. The service oriented architecture of SampleManager 10 facilitates integration with QMS and other enterprise-level systems to enhance communication and information transfer. The dynamic real-time dashboards available in SampleManager provide managers and operators with visibility into operations for faster, more informed decision-making.

Laboratory ISO 17025 Compliance Demonstrates Commitment to Quality

The example of the cereal recall demonstrates the consequences of introducing an off-spec product into the supply chain. In all likelihood, the offending party in this example was a subcontractor, begging the question how can an end user be assured that its intermediate products are manufactured in strict accordance with its own quality specifications? If the subcontractor had an ISO/IEC 17025:2005 certified laboratory, it could provide the assurance backed by the documentation to prove that intermediate products do in fact meet the specifications.

As a result of fluctuations in raw materials, hydrocarbon processing laboratories are becoming almost like third-party service laboratories. As such these labs must assure compliance of product(s) to specifications, making laboratory accreditation with standards such as ISO 17025:2005 no longer just nice to have, but a necessity to ensure conformance and customer satisfaction. Compliance with ISO 17025 demonstrates a commitment to quality, and provides customers the assurance that the laboratory's management

and technical requirements adhere to globally accepted best practices. The documentation produced by SampleManager LIMS confers credibility in testing practices and data quality to customers and regulatory authorities.

ISO 17025 requires a complete history of each piece of equipment including checks and calibrations performed prior to being placed in service and continue with detailed records of all calibrations, repairs, maintenance, and performance checks over the life of the device. A clear advantage for final product manufacturers is that utilizing certified ISO 17025 laboratories as subcontractors fulfills all the requirements as applicable to calibration and testing activities of an ISO 9001 quality management system. This enables the manufacturer to recognize the subcontractor as ISO 9001 certified for any work performed within the ISO 17025 scope. Quality audits of an accredited subcontractor are not required. SampleManager's statement of work (SOW) can be used to ensure that customer requests match the delivery of samples to the lab, and the delivery of results back to the customer. The SOW also links the work carried out on behalf of the customer to the agreed price list.

Conclusion

An enterprise LIMS offers value to organizations far beyond the laboratory walls. When designed with workflows in mind, LIMS allows users to control every stage of a product's testing and approval. As an integral component of a comprehensive quality management system, LIMS can help manufacturers achieve their quality targets and ensure that ISO compliance is met. Fewer defects, reductions in rework and scrap, and higher yields from raw materials are results that directly impact profitability. Satisfied customers are priceless.

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